

**Section II. (REMARKS)****Amendment of Claims to Comply with Examiner Spivack's Requirement in the March 22, 2005 Official Communication**

In response to the March 22, 2005 Office Communication in the above-identified application, requiring that “[T]he subject matter of the original claims be presented as new claims beginning with claim 46,” the claims have been amended herein to comport with such requirement.

Thus, claims 1-45 have been cancelled and new claims 46-59 have been introduced, as proposed by the Examiner.

Remarks are set out below concerning the October 18, 2004 Official Communication, since these remarks have not been considered on the merits in prior responses to the Office.

**Determination in the October 18, 2004 Official Communication of Non-Responsiveness of the August 2, 2004 Amendment to the March 2, 2004 Office Action, and Amendment of Claims Herein as Obviating Such Determination**

In the October 18, 2004 Official Communication, the August 2, 2004 Amendment filed in this application was determined to be non-responsive to the March 2, 2004 Office Action.

The Examiner based her determination on the following reasons stated in the October 18, 2004 Official Communication:

“The Amendment filed August 2, 2004 canceling all claims drawn to the elected invention, i.e., methods of combating movement disorder in a patient experiencing or susceptible to same, by administering a neurotransmission modulating composition comprising a 5HT antagonist and/or alpha-2 antagonist” ...

“The new claims are not readable on the elected invention because they are directed to methods of combating movement disorder in a patient experiencing or susceptible to such movement during treatment with a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication comprising administering mirtazapine, as well as compositions comprising (i) a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication and (ii) mirtazapine.”

The determination of non-responsiveness of the prior Amendment therefore appeared to rest on (i) a misapplication of the only election requirement of record, and (ii) the presence of a composition claim (now-cancelled claim 45, as a non-method claim) in the claims of the August 2, 2004 Amendment. The limitation of "during treatment with a dopaminergic medication, an anticonvulsant medication or an antianxiolytic medication" in the claims (in now-cancelled claim 31, from which now-cancelled claims 32-44 were directly or indirectly dependent) merely further narrowed the claim with respect to characterizing the patient (as being treated with the specified additional agents) in the claimed methodology, and did not in any way distort or defeat the prior election.

In fact, the only election requirement of record in the present application is the election of species requirement imposed by prior Examiner William Jarvis in the January 15, 2003 Office Action, wherein that Examiner stated that

"Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each class (i.e., a 5-HT antagonist and/or an  $\alpha$ -2 antagonist or one compound exhibiting both activities)."

In a Response filed February 18, 2003, the election was made as follows:

"In response, applicant elects 'one compound exhibiting both activities' and elects mirtazapine as a single disclosed compound, viz., 1,2,3,4,10,14b-hexahydro-2-methyl-pyrazino [2,1-a]pyrido [2,3-c]benzazepine.)"

This response was acknowledged by the present Examiner in the July 1, 2003 Office Action.

Since applicants have in the present Amendment canceled claims 1-45<sup>1</sup>, and added method claims 46-59 that are limited to mirtazapine, there is no infirmity of elected subject matter in the claims 46-59 now pending in the application.

**Patentable Character of Claims 46-59**

All of the new claims 46-59 are directed to the elected species, mirtazapine, which the examiner has indicated "to be free of the prior art" (page 2, lines 2-3 of the March 2, 2004 Office Action).

No new matter (35 USC 132) has been added.

Claim 46 recites a method of combating movement disorder in a patient experiencing or susceptible to same who is being treated with dopaminergic medication, anticonvulsant medication or antianxiolytic medication, said method comprising administering to the patient an effective amount of mirtazapine. Such claim is consistent with Examples 1-6. As mentioned, method claim 46 fully comports with the election requirement of record, and applicants' response thereto, of record. Claim 46 therefore has no infirmity as to its subject matter.

Concerning the dependent claims 47-59 under claim 46, the same are likewise fully consistent with and supported by the as-filed disclosure of the application.

The dopaminergic medication (claim 47) can include a dopa agonist (claim 48; Examples 2 and 3), with specific dopaminergic medication ingredients (claim 49) including levodopa (Example 6), levodopa in combination with carbidopa (Sinemet; Examples 1-3), or ropirinole (Example 2).

The anticonvulsant medication (claim 50) can include primidone (Mysoline; Example 4) (claim 55).

The antianxiolytic medication (claim 56) can include (Example 5) propranolol (claim 57), an SSRI (claim 58) or a benzodiazepine (claim 59).

---

<sup>1</sup> Such cancellation of claims 1-45 is made with the reservation of the right to file a further application directed to subject matter of such claims, during the pendency of the present application or during the pendency of a further continuing or divisional application based on and claiming the priority of the instant application.

The movement disorder can include bradykinesia (claim 51; Examples 1-3), tremor (claim 53; Examples 2-6), resting tremor (claim 52; Examples 2, 3 and 6), and action tremor (claim 54, Examples 4 and 5).

All pending claims 46-59 therefore embody the elected species.

**Rejection of Claims on Reference Grounds under 35 CFR §102(b) and 35 USC §103(a)**

In the March 2, 2004 Office Action, the previously pending elected claims 1-14, 16, and 18-30 were rejected on various grounds, including:

a rejection of claims 1-14, 16, 18, 23, 24, 26-28 and 30 "under judicially created doctrine as being drawn to an improper Markush group;"

a rejection of claims 1-14 and 18, 23, 24, 26-28 and 30 under 35 USC 112, first paragraph as non-compliant with the written description requirement;

a rejection of claims 3 and 16 under 35 USC 112, second paragraph as failing to particularly point out and distinctly claim the invention;

a rejection of claims 1-4, 6-12, 13, 26, 27 and 30 under 35 USC 102(b) as anticipated by Henry et al., Experimental Neurology; and

a rejection of claims 1-5, 6-14, 16, 18, 23-28 and 30 under 35 USC 102(b) as anticipated by Lin-Shiau et al., Pharmacol., Biochem. Behav.

These various rejections now are moot in view of the addition herein of claims 46-59, and cancellation of all other claims.

All pending claims 46-59 are now directed to the elected species, mirtazapine, which has been characterized by the examiner "to be free of the prior art" (page 2 of the March 2, 2004 Office Action).

Further, the pending claims 46-59, as discussed in preceding remarks, are based on and directly supported by the specific examples in the application. All claims 46-59 are now of proper form and fully in compliance with the requirements of 35 USC 112. No improper Markush group is present in any claim.

Accordingly, all claims 46-59 now pending in the application are patentable over the art and in condition for allowance. Favorable action therefore is requested.

Respectfully submitted,

  
\_\_\_\_\_  
Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicants

INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4164-101 CON